THE ARRIVAL OF ASP

AVERAGE SALES PRICE

Health plans are beginning to adopt the average sales price method of paying oncologists and other specialists for office-administered drugs. ASP is more transparent and has a smaller markup than its much maligned predecessor, average wholesale price. The speed of ASP uptake will affect everyone who makes, sells, prescribes, and takes these medications.

BY PATRICK MULLEN, *Senior Contributing Editor*

A long-standing trend in healthcare payment is that where Medicare leads, health plans tend to follow. Now it's happening again, this time with biologics and other drug therapies that are provided in physician offices and covered under Medicare Part B.

After years of intense legal challenges to the previous payment method based on average wholesale price, Congress changed how Medicare Part B pays for physician-administered infused and injected drugs as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, moving to the average sales price method. The change was driven in part by a steady increase in Part B spending on drug therapies, up from $6.5 billion in 2001 to $10.9 billion in 2004. Part of that increase was a result of the gap between estimated physicians' acquisition cost of drugs and the higher amount that Medicare reimbursed them. In 2001, the Government Accountability Office found that private purchasers received discounts averaging 13 to 34 percent less than AWP for 17 office-administered drugs, and even higher discounts on others.

The move to ASP in 2005 "resulted in substantial price savings for Medicare on nearly all drugs and those payment rate changes drove decreased spending," according to a Medicare Payment Advisory Commission report to Congress in January. Overall, MedPAC reported, Part B drug expenditures fell by $800 million from 2004 to 2005.

The Congressional Budget Office calculated that the Medicare Modernization Act would reduce estimated Medicare payments for cancer care over 10 years by $4.2 billion. But the Community Oncology Alliance, which represents cancer clinics, argues that the MMA's implementation dramatically overcorrected congressional intent. The alliance, citing PricewaterhouseCoopers data estimating that $14.7 billion will be cut from cancer care payments over this period, is pushing Congress to revise the ASP formula, report prices monthly instead of quarterly, and raise payments for services related to professional care and drug handling.

For most drugs administered by physicians, Medicare pays 106 percent of volume-weighted ASP — a rate that is beginning to serve as a benchmark for commercial plans. AWP is based on data reported by manufacturers and published in

such broadly available sources as First DataBank's Blue Book. ASP, in contrast, is a manufacturer's average price to all purchasers, net of discounts, rebates, chargebacks, and credits for drugs. ASP is determined using manufacturers' sales reports, which include information on total units sold and total revenue for each drug, and is subject to audit by Medicare.

"AWP had gone well beyond its usefulness," says healthcare strategist Kip Piper, president of the Health Results Group, in Washington, and a senior counselor with Fleishman-Hillard. "It was junk, and the federal government and state attorneys general sued pharmaceutical manufacturers over how they calculated their market prices that ultimately played out in government reimbursement." That, he says, resulted in the creation of yet another pricing metric: the ASP.

PRIVATE PAYER UPTAKE

Health plans' move to ASP puts greater financial pressures on oncology practices, which, in turn, could affect where patients receive cancer treatments and the quality of that care. There is general agreement that most health plans will move to ASP over the next few years, but the pace of adoption varies widely across the country.

"One of the primary determinants of which plans adopt ASP is their share of the covered lives in a market," says Thomas Baker, MPA, partner and senior vice president of client strategy and analytics with the Zitter Group, in San Francisco. "Large national payers like Aetna or United, whose covered lives are spread over 300 markets and are highly dependent on their network integrity, don't have as much leverage to force oncologists to do anything. ASP is taking off with plans that have 750,000 to 1 million members and control the majority of people in their markets." He cites markets like Rochester, N.Y., and Birmingham, Ala., as examples, and notes that some Blues plans in the Southeast control close to 65 percent of covered lives in their states. "They can simply say to physicians, 'This is what you're getting.'"

Each fall, Health Strategies Group in Lambertville, N.J., surveys MCOs on trends in specialty pharmacy

PHOTOGRAPH BY MICHAEL PILLA

"It's just a matter of time before all plans follow suit" to adopt ASP, says Sharad Mansukani, MD, chief strategy officer at Nation's Health.

PHOTOGRAPH BY PETER HVIZDAK

"What we've learned on the Medicare side is that ASP and professional fees at Medicare rates are unsustainable," says Dawn Holcombe, MBA, senior vice president of payer relations and quality programs at Supportive Oncology Services, and executive director of the Connecticut Oncology Association.

management. Last fall's survey of 60 health plans represented 53 million covered lives, well distributed across national plans, large regional independents, Blues plans, and large Medicare and Medicaid plans. Of the plans surveyed, 54 percent intend to use ASP in 2007.

But intent and reality don't always coincide. Howard Flushman, Health Strategies Group's director of research for specialty pharmacy management, cautions that because of plans' differing abilities to negotiate new fee schedules in their local communities, more plans *say* they will move to ASP than will actually make the change. One survey respondent, a pharmacy director at a national MCO, said the plan is "trying to go [to ASP], but there's reluctance with our providers. If you change your pricing strategy, you need to open up some of those contracts, and when you open up that contract, you don't just open it up for that. You open it up all the way."

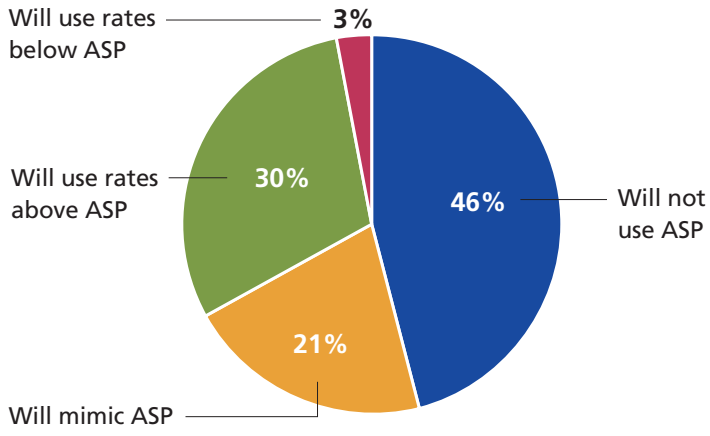
"MCOs with a plethora of oncologists in their networks can afford to switch to ASP sooner, because they can afford to refine their oncology network without losing access to some oncologists," says Sharad S. Mansukani, MD, chief strategy officer at Nations Health, a Sunrise, Fla.-based supplier of prescription drugs and medical supplies to Medicare plans and beneficiaries. Mansukani served as senior advisor to the administrator of the Centers for Medicare and Medicaid Services and helped to draft the MMA. Plans with fewer oncologists will move a bit slower, he says, "but it's just a matter of time before all plans follow suit."

ONCOLOGISTS: NOT ENOUGH

However gradual, the change to ASP is coming faster than oncologists and other specialists would like. For oncologists, for whom higher drug payments under AWP subsidized what they say has been chronic underpayment for professional services, ASP raises two key questions: Will health plans mimic Medicare's payment rate of 106 percent of ASP? And, will plans simultaneously increase payments for

Half of plans using ASP this year

As part of Health Strategies Group's annual survey of managed care pharmacy trends, 60 health plans representing 53 million covered lives were asked last fall about their plans to use ASP in 2007, and whether they would pay at, above, or below Medicare's payment levels.



SOURCE: *MCO TRENDS IN SPECIALTY PHARMACY MANAGEMENT, FALL 2006,* HEALTH STRATEGIES GROUP, LAMBERTVILLE, N.J.

professional services? The answers will help to determine if smaller oncology practices can stay in business in the new payment environment. Respondents to the Health Strategies Group survey who plan to introduce ASP were split on how much they intend to pay (see chart above).

"You may see press releases from plans saying they're going to stay close to the Medicare payments, but when it's all said and done, it won't look like that because of what we've learned on the Medicare side, which is that ASP and professional fees at Medicare rates are unsustainable," says Dawn Holcombe, MBA, senior vice president of payer relations and quality programs at Supportive Oncology Services, and executive director of the Connecticut Oncology Association. "Practices that have a higher percentage of Medicare beneficiaries in their patient populations are not faring well. These are small businesses that are going under."

"Of the payers that have adopted ASP, few have kept the rate at 6 percent over ASP," says Mary Kruczynski, director of policy at the Community Oncology Alliance, in Washington. "Plans are generally paying some percentage above Medicare." A recent study underway at the alliance has revealed a growing trend in the adoption of an ASP plus 6 percent model, according to Kruczynski. Reports from Arkansas, California, and New Jersey revealed recent or planned fee schedule modifications reflective of the ASP plus 6 percent rate, and it is anticipated that others will follow suit in the near future.

But the Zitter Group's research indicates that health plans are taking a tougher line, Baker says. "We're hearing anecdotally that plans are paying some percentage above ASP plus 6 percent, but our research shows that health plans report ASP plus 6 percent as their actual rate. They don't see the need to make it any higher."

That's bad news for oncology practices, particularly smaller ones. "Oncologists are feeling the brunt of the change from AWP to ASP-based reimbursement," says Mitchell DeKoven, MHSA, director of reimbursement and market access for ValueMedics Research, a unit of IMS Health, in Falls Church, Va. "Oncologists who have analyzed the financial impact of this change on their practices are taking several steps: being more diligent in collecting copayments, verifying insurance benefits, obtaining rebates, and referring patients without supplemental insurance (who might not be able to afford the copayment) to other settings of care, such as a hospital outpatient department."

Even before plans began switching to ASP, oncology practices took a hit from reduced payments under Medicare, some being forced to "close satellite facilities or even main offices, merge with other groups, or sell to hospitals because they can't remain above water," Holcombe says. She cites a solo oncologist in Connecticut who first closed his infusion center "because of the inadequacy of the ASP plus 6 percent formula to cover his [purchase] costs," and then his full practice because the professional rates by Medicare and private payers "were inadequate to sustain a practice without infusion services." The closest oncologist, she says, was nearly an hour's drive away on winding roads.

Stories like this may fall on unsympathetic ears at health plans, says Baker, who notes that little love is lost between MCOs and oncologists. "I've heard plans say explicitly to oncologists, 'That's your own fault. Why didn't you raise your rates over the last 20 years?'"

Roughly one quarter of oncology practices have three or fewer physicians, Flushman at Health Strategies Group notes, and these practices are most likely to refer patients who need infusions elsewhere, such as hospital outpatient clinics; independent outpatient infusion sites; larger, more capital-strong physician practices; infusion sites owned and operated by large home care companies; and other locations. Such referrals could raise a red flag for health plans in a way that's less likely to happen with Medicare, Holcombe says. "Medicare and private insurers have completely different perspectives on the prospect of patients going to a hospital for their care," she says. "Medicare Part A and Part B don't speak to each other very well, so moving patients from one setting to the other is not a significant issue for CMS, though it is to the practice, the hospital, and the patient. Private plans recognize that there is a significant difference as to whether care is delivered in a hospital or in a physician office, and clearly prefer to keep patients out of the hospital as much as possible." Although hospital clinics certainly can provide high-quality care, they're often not set up to deal with large numbers of patients, don't provide the same continuity of care as a doctor's office — and may not want the referrals, she adds. Several hospitals across the country recently have informed oncologists of limitations on referrals in terms of volume, geography, and treatments.

POTENTIAL CONSEQUENCES

Lower prices for cancer drugs could determine which drugs are

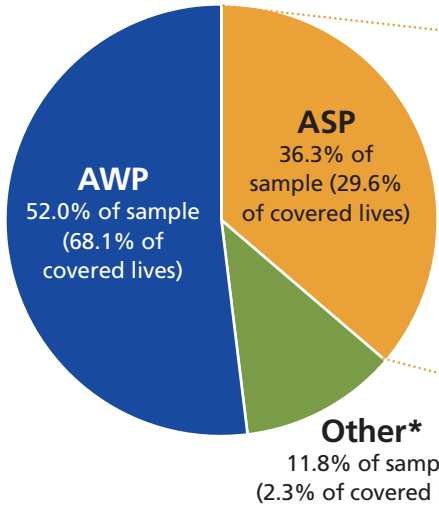
Payer-reported ASP rates for oncology reimbursement

One third of commercial organizations report using average sales price, with the Medicare rate of ASP+6 percent as the most common payment, according to a survey by the Zitter Group.

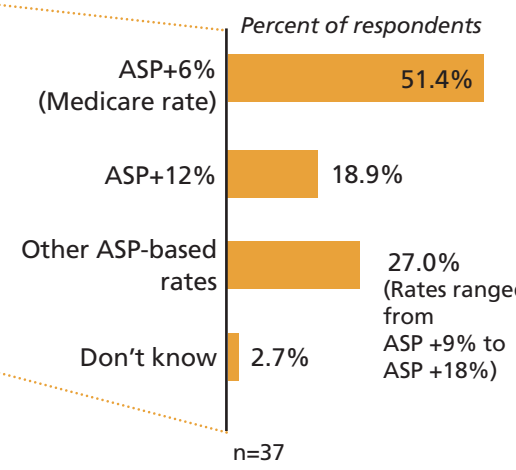
Current oncologist reimbursement policy

Question: "Currently, which physician payment methodology does your organization use to reimburse oncologists for your commercial population?"

Payers (n=102)



Question: "At what rate does your organization currently reimburse relative to ASP?"



*12 payers report using a combination of reimbursement methodologies, such as contracted rates for specific products or a percent of billed charges

SOURCE: *MANAGED CARE ONCOLOGY INDEX* (WINTER 2007), THE ZITTER GROUP, SAN FRANCISCO

worth the research and development costs for biotech manufacturers. "Does it really help you to be the twelfth EGFR blocker to come to market if physicians aren't making a lot of money and your efficacy isn't any better than the others?" asks Baker, who thinks physicians will be less likely to use an expensive drug that doesn't have a dramatic effect on the survival rate and has significant side effects. Physicians and payers surveyed by the Zitter Group most often cited cetuximab (Erbitux) as an example of such a drug.

Conversely, products like trastuzumab (Herceptin) and imatinib mesylate (Gleevec) are less vulnerable. "In both cases, the target for the drug is unique to the patient population," Baker says. "There are tests for both of them, so patients who don't have a particular mutation don't get the drug. Therefore, patients respond very effectively to those drugs, and the off-label problem is reduced."

Though the full impact of ASP on payers, physicians, patients, and manufacturers won't be known for a few years, the rules of the game are changing. One further twist is possible, in the form of an effort by Medicare to breathe new life into the Competitive Acquisition Program. One scenario would allow physicians to order Part B-covered drugs from a vendor paid directly by Medicare, theoretically freeing practices from the administrative costs of buying those drugs. "CAP didn't take off because the big distributors — McKesson, Amerisource, and Cardinal — didn't sign up," says Mansukani, of Nations Health. "Only Bioscrip agreed to participate in CAP during the first go-around." He foresees Medicare trying a second version of CAP, reconfigured — and probably renamed — to attract the major distributors.

In the meantime, physicians will have to cope with ASP. "The big deal conceptually is having a fixed fee schedule for drugs where one never existed before," says Flushman. "That idea is not going to go away, regardless of what happens to the particular methodology of ASP. The mindset has been changed, the precedent has been set." BH

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How raising AWP led to its fall

Given that its initials are commonly derided as standing for "ain't what's paid," perhaps it's not surprising that the average wholesale price methodology is falling by the wayside. AWP was under growing legal scrutiny well before the Medicare Modernization Act shifted Part B payments to the average sales price method in 2005.

AWP failed to reflect real drug-acquisition costs, had no legally binding definition, and contributed to rapidly rising Part B drug costs. Physicians bought the drugs, administered them to patients, charged beneficiaries their deductibles and 20 percent Part B coinsurance, and billed Medicare for the drug and the office visit, receiving 95 percent of AWP. This "buy-and-bill" approach was widely criticized by government watchdogs because Medicare ended up paying far more for the drugs than other payers, leaving patients with higher copayments.

By 2001, more than 20 manufacturers were under investigation for inflating AWP rates. Reports issued by the Health and Human Services inspector general and the Government Accountability Office detailed how Medicare spent hundreds of millions of dollars more for drugs covered under Medicare Part B than if they paid the same prices as private insurers.

In 2001, TAP Pharmaceutical Products agreed to pay $875 million to settle charges that it had inflated prices and had engaged in improper sales and marketing practices to induce doctors to prescribe the prostate cancer drug leuprolide (Lupron). TAP also settled charges of filing false claims with Medicare and Medicaid, accounting for $560 million of the settlement. As part of a corporate integrity agreement negotiated with HHS, TAP agreed to start reporting accurate pricing information showing its true average sales price to Medicare and Medicaid.

Two years later, use of ASP for Medicare Part B was written into law. In 2006, First DataBank, one of the leading drug-price reporting firms, settled a class action complaint alleging manipulation of AWP prices based on the ratio of AWP to wholesale acquisition cost, the price reported by drug manufacturers as the average amount paid by pharmacies to wholesalers. As part of that settlement, First DataBank agreed to stop publishing AWP data within two years.